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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,576	01/02/2002	Yonghua Zhang	47237/DBP	7268

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,576	ZHANG, YONGHUA	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT FOR PRIORITY, IDS, PRELIMINARY AMENDMENT, STATUS OF THE APPLICATION AND THE CLAIMS

1. This application is filed under 35 U.S.C. 371 on 1/2/02 having a filing date of 3/2/00 of PCT/CN00/00041. Acknowledgment is made of Applicant's claim for priority based on Chinese application number 99102848.1 having a filing date of 3/9/99. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The Information Disclosure Statement (IDS) and Form PTO-1449 filed 1/2/02 and the preliminary amendment filed 2/11/02, respectively are acknowledged, entered and considered. Claims 1-13 are present for examination

THE SPECIFICATION, CLAIMS AND ABSTRACT ARE A LITERAL TRANSLATION

2. A substitute specification including abstract in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. Also, pages 4-11 should be substituted because 37 CFR 1.52(b) requires that the top of each page of the specification, including claims must have a margin of at least approximately ¾ inch (2 cm) to prevent possible mutilation of text when papers are punched for insertion in a file wrapper. Hence, the top margins of the above-cited pages are not readable. A statement that it contains no new matter must accompany the substitute specification filed. Further, the claims are generally narrative and indefinite and fail to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

NUMEROUS ERRORS IN THE SPECIFICATION

3. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: page 1, first paragraph "where appropriated"; page 1, second paragraph, "about the each component"; page 2, line 9, "is poor absorbed"; page 2, line 15, "Fuit juice"; page 2,lines 15-16, "patent's body condition".

OBJECTIONS TO TRADEMARKS AND THEIR USE

4. The use of trademarks "SANDIMUN NEORAL" and "IMPLANTA" have been noted in this application. The trademarks have not been accompanied by their generic terminologies. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner which might adversely affect their validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the articles referred by the trademarks. These descriptions requirement are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 11, the phrase "such as" render the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 1 and 13, the phrases "etc." and "and so on", respectively render the claims indefinite because the claims include elements not actually disclosed (those encompassed by "etc., and so on"), thereby rendering the scope of the claims unascertainable. See MPEP § 2173.05(d).

Claim1 is indefinite and confusing in the recitation "a solvent or a co-surfactant such as ethanol, propylene glycol and the mixture of them" because it is not clear whether the solvent is ethanol, PEG and mixture thereof or the co-surfactant is ethanol, PEG or mixtures thereof. Appropriate clarification is required.

Claim 1 is indefinite and vague in the recitation ", and fish oil as;". It appears that something is missing. Appropriate correction is suggested.

Claim 1 is indefinite in the recitation "where appropriated". Amendment of the claim to recite "wherein appropriate" would obviate this rejection.

Claim 2 is indefinite and confusing in the recitation "said solvent or co-surfactant is ethanol, propylene glycol or a mixture of them" because it is not clear whether the solvent is ethanol, PEG and mixture thereof or the co-surfactant is ethanol, PEG or mixtures thereof. Although, the scope of claim 2 appears to be narrower than the scope of claim 1 because of the phrase "such as" which may include other solvents or co-surfactants. However, for the reasons stated above, the phrase "such as" renders the claim indefinite. Thus, it appears that claim 2 does not further limit claim 1. Appropriate correction is suggested.

Claim 5 is indefinite in the recitation "wherein said the surfactant". Amendment of the claim to recite "wherein said surfactant" is suggested.

Claim 5 contains the trademark/trade names "Tween and Myrj". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade names are used to identify/describe surfactants, and, accordingly, the identification/description is indefinite.

Claims 6-8 and 10 are indefinite in the recitation "wherein as the lipophilic component". Amendment of the claims to recite "wherein the lipophilic component" is suggested.

Claim 10 is indefinite in the recitation the acronym "DHA". Use of the full terminology at least in the first occurrence would obviate this rejection.

Claim 12 recites the limitation "wherein said ratio of cyclosporin", in line 1. There is insufficient antecedent basis for this limitation in claim 1 or claim 12.

CLAIM REJECTIONS-35 U.S.C. § 102(b)

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Komiya et al. (U.S. Patent No. 5,504,068).

The instantly claimed invention as claimed in claims 1-6 and 11–13 is directed to a pharmaceutical formulation formulated for soft capsule, ointment, eye-drop, oral solution or injection, said formulation comprising a cyclosporin as an active ingredient, a solvent or a co-surfactant, wherein the surfactant has a hydrophilic-lipophilic balance (HLB) value of 10 to 19 as solubilizer, and a lipophilic component selected from organic

acids having the properties as recited in claims 1, 6 and 11, and wherein the ratio of cyclosporin to the purified water is 1:0-1000 (w/w) (claim 12).

Komiya et al. disclose a pharmaceutical formulation used in topical administration containing a) cyclosporin as an active ingredient from approximately 0.1% to 10% by weight; b) an organic solvent from 1% to 20% by weight; c) an ester of fatty acid from 1% to 15% by weight; d) oily substance from approximately 15% to 30% by weight; e) surfactant from approximately 1% to 20% by weight having an HLB of 9 to 18; f) filler from 0% to approximately 10% by weight; and g) sterilized water from approximately 30% to 75% by weight. Thus, the reference clearly discloses pharmaceutical composition containing cyclosporin together with organic acids, oily substances including fish oil, solvents, surfactants and water for use as topical formulation (See e.g., abstract, cols.6-9 and Example 1) as directed to claims 1-6 and 11-13, as such the prior art anticipates the claims as drafted.

7. Claims 1-6, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Woo (U.S. Patent No. 5,589,455).

The instantly claimed invention as claimed in claims 1-6, 11 and 13 is directed to a pharmaceutical formulation formulated for soft capsule, ointment, eye-drop, oral solution or injection, said formulation comprising a cyclosporin as an active ingredient, a solvent or a co-surfactant, wherein the surfactant has a hydrophilic-lipophilic balance (HLB) value of 10 to 19 as solubilizer, and a lipophilic component selected from organic acids having the properties as recited in claims 1, 6 and 11.

Woo discloses a soft capsule pharmaceutical formulation containing a) cyclosporin as an active ingredient; b) polyethylene glycol as co-surfactant; c) a mixture of fatty acids having C_8-C_{20}, preferably C^{18}-C_{20}; and d) a having an HLB value of 10 to 17. Thus, the reference clearly discloses pharmaceutical composition containing cyclosporin together with organic acids, oily substances including fish oil, solvents, surfactants and water as pharmaceutical formulation (See e.g., abstract, cols.3-6 and claim 1) as directed to claims 1-6, 11 and 13, as such the prior art anticipates the claims as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya et al. (U.S. Patent No. 5,504,068).

The reference of Komiya et al. as discussed above discloses a pharmaceutical formulation used in topical administration containing a) cyclosporin as an active ingredient from approximately 0.1% to 10% by weight; b) an organic solvent from 1% to 20% by weight; c) an ester of fatty acid from 1% to 15% by weight; d) oily substance from approximately 15% to 30% by weight; e) surfactant from approximately 1% to 20%

by weight having an HLB of 9 to 18; f) filler from 0% to approximately 10% by weight; and g) sterilized water from approximately 30% to 75% by weight. Thus, the reference clearly discloses pharmaceutical composition containing cyclosporin together with organic acids, oily substances including fish oil, solvents, surfactants and water for use as topical formulation (See e.g., abstract, cols.6-9 and Example 1) as directed to claims 1-6 and 11-13.

The reference of Koyima et al. differs from claims 7-10 in not teaching the use of specific fatty acids as claimed in claims 7-9 and the content of fish oil of claim 10, however, the reference on col. 6 teaches various fatty acids having from 2-18 carbon atoms in pharmaceutical formulation for use as topical administration in combination with cyclosporin as an active agent. Thus, it is the Examiner's position that given the general teachings of the reference (i.e., use of any kind of fatty acids having 2-18 carbon atoms in pharmaceutical formulation comprising cyclosporin as an active ingredient); one of ordinary skill in the art would have easily selected the claimed specific fatty acids of claims 7-9 for the intended purpose of using a pharmaceutical composition containing cyclosporin. With respect to the limitation of claim 12, the reference on col. 7, lines 13 to 21 discloses the content of oily substance (which includes fish oil) may range from 1 part to 10 parts by weight, and as such overlaps with the limitation of 70% DHA (w/w/) of claim 12.

Therefore, in view of the above and in view of the teachings of the prior art, one of ordinary skill in the art at the time the invention was made would have been motivated to employ the teachings of the prior art to choose the specific fatty acids as claimed in claims 7-9 and the specific content of fish oil to obtain the known and recognized functions and advantages thereof for the intended purpose of formulating a

pharmaceutical formulation comprising cyclosporin as an active ingredient, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRSPONDANCE

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications..

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

AAM Mohamed/AAM
November 17, 2003